DEFENSE THREAT REDUCTION AGENCY
AND
UNITED STATES STRATEGIC COMMAND CENTER
FOR COMBATING WEAPONS OF MASS DESTRUCTION
8725 JOHN J. KINGMAN ROAD, STOP 6201
FORT BELVOIR, VA 22060-6201

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Director, Division of Spent Fuel Management
Office of Nuclear Material Safety and Safeguards
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

SUBJECT: QUALITY ASSURANCE PROGRAM FOR PACKAGING AND TRANSPORTATION OF FISSLE MATERIAL

1. Quality Assurance Requirements

This document establishes the Quality Assurance Program (QAP) for DTRA/SCC-WMD. The QAP is to be implemented through the Director, J4/8C, Acquisition, Finance, and Logistics Directorate to the Director, J4E, Environment, Safety, and Occupational Health (ESOH) Department. As stated in Title 10 Code of Federal Regulations Part 71 (10 CFR 71) Subpart H, the QAP is applicable to the design, purchase, fabrication, handling, shipping, storing, cleaning, assembly, inspection, testing, operation, maintenance, repair, and modification of components of packaging that are important to safety for the use in the transportation of radioactive materials (RAM). Design, fabrication, assembly, and testing of the packaging by the DTRA/SCC-WMD are not permitted by the QAP.

Quality Assurance (QA) comprises all of those planned and systematic actions necessary to provide adequate confidence that a system or component will perform satisfactorily as designed. Quality assurance includes quality control (QC), which includes those QA actions related to control of the physical characteristics and quality of the material or component to predetermined requirements.

Each of the applicable criteria given in Subpart H and any specific provisions that are applicable to activities conducted by the DTRA/SCC-WMD, including procurement of packaging, shall be established, maintained, and executed according to the QAP. Applicable criteria shall be applied in a graded approach, i.e. to an extent that is consistent with its importance to safety. Safety control will be commensurate with the radioactivity and the form of the material being shipped. The materials to be shipped by the DTRA/SCC-WMD in accordance with 10 CFR 71.22 are considered "sealed sources" and the fissile material cannot be readily separated from the structure of the source.

Safety control will be applied to each shipment through the use of supporting written guidance (procedures, instructions, checklists, etc.) and training to the degree required to be certain the shipment will be accomplished safely. Training sufficient to meet 49 CFR, the Defense Transportation Regulations, and any additional requirements as specified in DTRA/SCC-WMD License, 45-25551-01 will be completed for affected personnel.

The QAP shall be filed with the NRC Office of Nuclear Material Safety and Safeguards (NMSS) and will be established, maintained, and executed in a manner that satisfies applicable regulatory requirements. 10 CFR 50 Appendix B is not applicable to DTRA/SCC-WMD.

DTRA/SCC-WMD does not own or directly use radiographic exposure devices regulated under 10 CFR 34. If in the future it becomes prudent for the DTRA/SCC-WMD to own or perform radiography with such devices, an appropriate license will be obtained by which will include a program for transport container inspection and maintenance.

2. Quality Assurance Organization

The QAP Manager (QAPM) shall retain and exercise responsibility for the QAP applicable to the packaging and containers in which fissile material will be shipped. The work related to the QAP will be completed by the Environment, Radiation, and Safety (ERS) Office (J4EE). All work performed for the QAP shall clearly establish and delineate, in writing, the authority and duties of persons and organizations performing activities affecting the safety related functions of structures, systems, and components. These activities include performing the functions associated with attaining quality objectives and the QA functions.

The QA function of assuring that an appropriate QAP is established and executed shall be met as follows:

a. DTRA/SCC-WMD Radiation Safety Officer (RSO), will serve as the Quality Assurance Program Manager (QAPM) and shall be the person responsible for preparing the QAP and related documents. The QAPM shall coordinate operations performed under the QAP.

b. Chief, ERS (J4EE), and staff, provides review of the QAP and related documents

c. Chief, ERS (J4EE), serves as a point of contact for the correction of reported deficiencies.

d. Chief, ERS (J4EE), provides supervision of the work performed by the QAPM and ERS (J4EE) staff.

The QA process for verifying adherence to procedures of activities affecting safety-related functions shall include:

a. Personnel performing periodic QA/QC and inspection functions.

b. Trained and qualified Site-RSOs offering direct supervision over personnel packaging fissile materials for shipment.

c. At least one designated individual will be assigned to perform QA/QC and Inspection functions for shipments of fissile material made under the QAP. Personnel performing QA/QC and Inspection functions shall not participate in the actual physical receipt of the packaging, loading, and preparation for shipment or serve as Audit personnel. Personnel performing QA/QC and Inspection functions may include J4EE staff members. At least one individual will perform audits of shipment(s) of fissile material made under the QAP. Audit personnel shall not participate in the actual physical receipt of the packaging, loading and preparation for shipment, or perform QA/QC and Inspection functions.

Other QA organization requirements include:

a. Allowing personnel performing the work or QA/QC and Inspection functions, under the QAP the authority to halt operations and to refer safety matters to the QAPM for resolution. Personnel performing QA/QC and Inspection functions, the Chief, ERS (J4EE) or the QAPM may recommend or provide possible solution(s) to problems. If the Chief, ERS (J4EE) or the QAPM is not able to satisfactorily resolve the matter, the Director, ESOH (J4E) shall be consulted.

b. Allowing the QAPM and Site-RSOs the authority to cease operational functions with justifiable cause and directing continuance of the operation only upon resolving the cause for the cessation of activities.

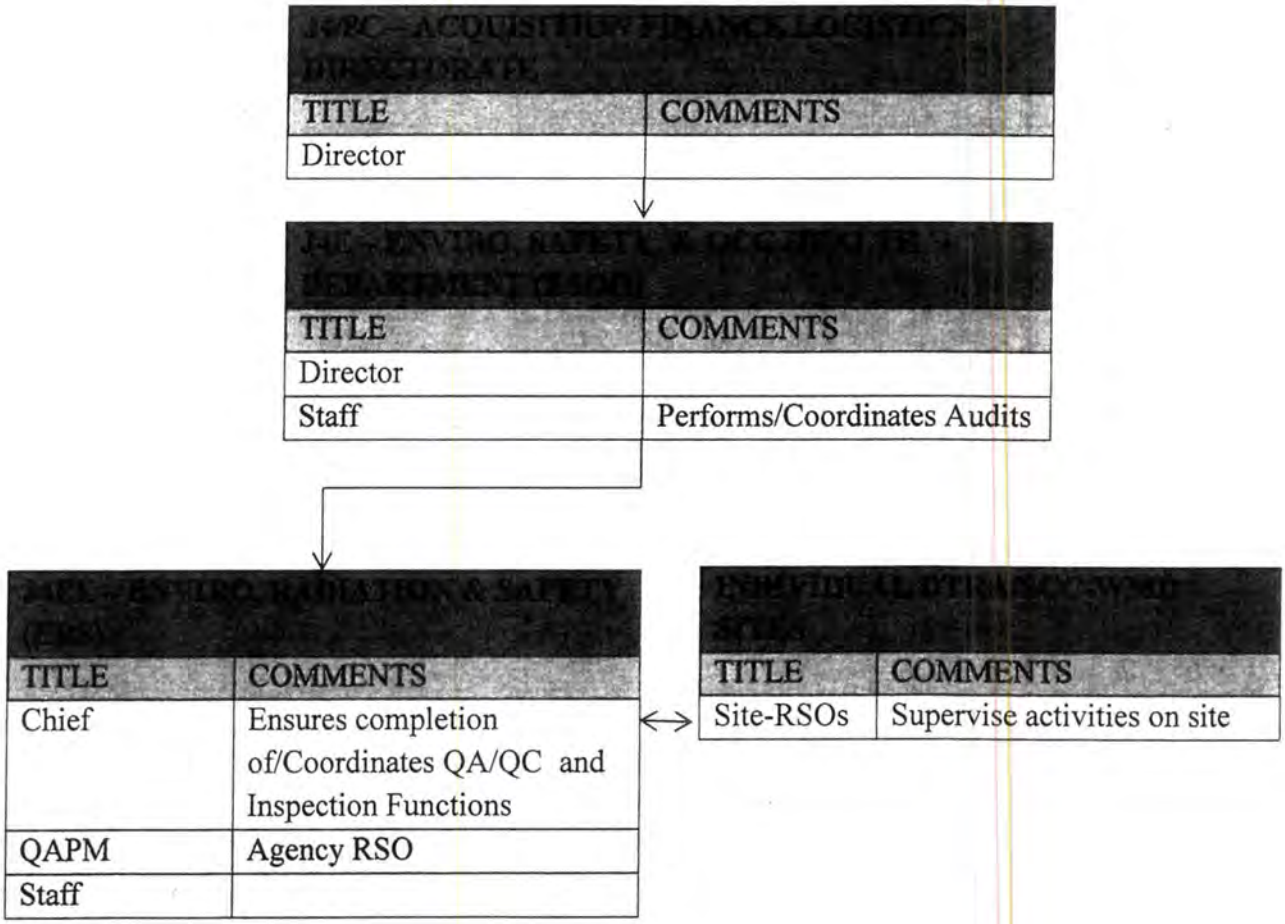
c. Verification of solutions to problems by the workers, Personnel performing QA/QC and Inspection functions, and/or the QAPM by use of approved supporting documentation, as necessary.

d. Site-RSOs perform compliance activities to ensure personnel performing transportation functions are properly trained to meet transportation and QAP requirements. Site-RSOs are responsible for providing supervision over each trained and certified shipper to ensure all established procedures for the shipment of DTRA/SCC-WMD owned fissile materials are accomplished safely during all aspects of the pre-transportation, transportation, and post-delivery stages.

e. Ensure QAPM provides the proper oversight to support Site-RSOs.

f. Maintain the QAP organization as depicted in Figure 1, indicating the reporting and communication lines.

FIGURE 1
QUALITY ASSURANCE PROGRAM ORGANIZATIONAL CHART



DIRECTOR, J48C, ACQUISITION, FINANCE, AND LOGISITICS
ESOH—ENVIRO, SAFETY & OCC HEALTH (J4E)
ERS—ENVIRO, RADIATION & SAFETY (J4EE)
QAPM—QUALITY ASSURANCE PROGRAM MANAGER
SITE-RSOs—SITE RADIATION SAFETY OFFICERS

3. Quality Assurance Program

This QAP will be established, maintained, and executed by the Director, ESOH (J4E) as required by 10 CFR 71 Subpart H, DTRA/SCC-WMD Policy, and NRC Material License. The QAP shall be implemented during the period in which the packaging is used.

The QAP applies to the following materials and components:

a. Procurement of packaging for fissile materials including the design, fabrication, assembly, and testing of such packaging by a vendor approved for those activities by the NRC. Design, fabrication, assembly, and testing of the packaging by the DTRA/SCC-WMD are not permitted by the QAP.

b. Shipment of any fissile material in Type A packaging are performed in accordance with approved procedures and guidance written to meet requirements in applicable federal and State regulations (e.g. 10 CFR 20, 10 CFR 30, 10 CFR 70, 49 CFR).

Major organizations and personnel and their functions in the QAP are listed below:

a. Director, ESOH (J4E) is responsible for the QAP and will perform QAP Audit functions. The ESOH (J4E) includes ERS (J4EE), QAPM and staff members. If the QAPM is not able to satisfactorily resolve safety problems, the Chief, ERS (J4EE) shall be consulted.

b. QAPM is responsible for preparing the QAP and related documents, such as procedures and checklists. The QAPM coordinates operations performed under the QAP and supporting documents. The QAPM resolves any safety questions related to shipments of fissile material made under the QAP and related documents. The QAPM has the authority to cease operational functions with justifiable cause and shall direct continuance of the operation only upon resolving the cause for the cessation of activities.

c. Chief, ERS (J4EE), is responsible for providing assistance to the QAPM. The Chief, ERS (J4EE) and the Radiation Safety staff members review the QAP and support documents and may serve as QA/QC and Inspection personnel.

d. Director, J4E, exercises overall supervision of the work performed by ERS (J4EE) staff under the QAP and any related documents, including problem identification and resolution. Personnel performing QA/QC and Inspection functions are appointed to ensure that the actions required by the QAP and related procedures are being followed. Personnel performing QA/QC and Inspection functions shall not participate in the actual physical receipt of the packaging, loading and preparation for shipment, or serve as Audit personnel. Personnel performing QA/QC and Inspection functions may raise questions and concerns and have the authority to halt operations for activities conducted under the

QAP and shall refer those matters to the QAPM for resolution. Personnel performing QA/QC and inspection functions may suggest possible solution(s) to problems.

e. Audit personnel are appointed to review documentation of shipments made under the QAP. Audit personnel shall not participate in the actual physical receipt of the packaging, loading and preparation for shipment; or serve as QA\QC and Inspection personnel. Audit personnel may raise questions and concerns on activities conducted under the QAP and shall refer those matters to the QAPM for resolution. Personnel performing audit functions may suggest possible solution(s) to problems.

f. The activities and quality of materials and components identified in the QAP shall be controlled to an extent consistent with their importance to safety and as necessary to assure conformance to the approved design of each individual package used to ship fissile material.

g. Activities affecting quality shall be accomplished under controlled conditions and include the use of appropriate equipment, suitable environmental conditions (such as adequate cleanliness), and assurance that all prerequisites have been satisfied. Special controls, processes, test equipment, tools, and skills shall be taken into account to attain the required quality. This requirement is primarily met by the preparation, review, and approval of and adherence to the QAP and support documents (such as procedures, instructions, and checklists).

Other considerations for support documents include:

a. Information provided from the packaging provider, e.g. packaging documentation and certification.

b. Safety measures commensurate with the shipment.

c. Complexity and use of the package and its components, the impact of malfunction or failure of items, design and fabrication complexity or uniqueness of items, surveillance over processes and equipment, inspection and testing of items, and quality history and degree of standardization of items.

d. Qualification or certification of equipment and personnel, (e.g. equipment rating and personnel training) including proficiency testing of personnel (e.g. use of equipment, mock-up training).

e. Handling instructions (e.g. package assembly and loading, unloading and opening of the package, transport and storage).

f. Required records and forms.

Other requirements of the QAP and applicable regulations:

Based upon the information accumulated on the packaging and the activity to be performed; required supporting documents are prepared by the QAPM and validated if possible. The supporting documents are then reviewed and approved before being used. The support documents are then used by affected personnel to control the activities and to attain the required quality.

The status and adequacy of the QAP and support documents are reviewed by the QAPM, Chief, ERS (J4EE), and staff.

a. Every five years.

b. Following major regulatory changes.

c. Prior to executing the QAP or a supporting document.

d. Changes to the QAP, including documents and procedures, are reviewed by the Chief, ERS (J4EE) and staff, and approved by the Director, ESOH (J4E).

4. Package Design Control

The QAP is not applicable to packaging owned by another party. The ESOH (J4E) does not anticipate the undertaking of packaging design, fabrication, assembly, and proof of design testing. If in the future it becomes prudent for the Chief, ERS (J4EE) to undertake any or all of these QA functions, the QAP will be revised accordingly. Only approved packaging shall be used for fissile material shipments. Changes to approved packaging or conditions of use are not permitted.

5. Procurement Document Control

Only approved packaging shall be used for fissile material shipments. The packaging supplier will be required to furnish evidence of compliance with 10 CFR 71 Subpart H, packaging documentation required by 10 CFR 71, and/or the Certificate of Compliance (CoC) for the packaging. The packaging supplier shall be requested to furnish other information (tools,

equipment, checklists, etc.) that would facilitate the safe handling and use of the packaging and satisfactory evidence that the packaging was designed, fabricated, and tested, etc., in accordance with an approved QAP. The requests and receipts will be documented by the QAPM.

6. Instructions, Procedures, and Drawings

Instructions, procedures, and drawings will be prepared and documented for actions affecting quality as applicable. Sufficient detail in describing the sequence of events essential to achieving the desired quality objective will be provided. These supporting documents are reviewed and approved before being used. These supporting documents are then used by affected personnel to control the activities and to attain the required quality. Quantitative or qualitative acceptance criteria for determining that important activities have been satisfactorily accomplished shall be included in the related documents. Changes shall be made so that these support documents shall conform and be consistent with the degree of safety control required for the fissile material to be shipped. Applicable support documents shall be reviewed prior to use by affected personnel, including radiation safety measures and actions to be taken in the event of an undesired occurrence. If required, arrangements for transportation of the fissile material shipment by a firm possessing a NRC approved transportation security plan shall be coordinated through the ESOH (J4E). This plan shall be verified as fulfilling the specific requirements of the fissile material shipment to be made.

7. Document Control

The QAP and support documents are prepared by the QAPM and reviewed by the ERS (J4EE) staff. Changes to the QAP are reviewed and approved by the ESOH Director, (J4E). The status and adequacy of the QAP and support documents are reviewed by the QAPM and ERS (J4EE) staff prior to being used. Copies of valid, approved documents are distributed by the QAPM for use by authorized personnel at the location where the prescribed activity is being performed.

8. Control of Purchased Material, Equipment, and Services

The QAPM is responsible for the following:

a. Measures to assure that material, equipment, and services purchased directly or through contractors and subcontractors conforms to the procurement documents shall be established.

b. Provisions for source evaluation, selection, and objective evidence of quality furnished by the contractor or subcontractor, inspection at the contractor or subcontractor source, and examination of the products on delivery shall be included, as appropriate.

c. Documentary evidence that the material and equipment conforms to the procurement specifications before installation or use of the material and equipment shall be available. Such documentary evidence shall be sufficient to identify specific requirements met by the purchased material and equipment and shall be retained for the life of the package to which it applies.

d. Assessment of the effectiveness of the control of quality by contractors and subcontractors shall be made at intervals consistent with the importance, complexity, and quantity of the product or services purchased.

9. Identification and Control of Materials, Parts, and Components

The ESOH (J4E) does not anticipate the undertaking of packaging design, fabrication, assembly, and proof of design testing. If in the future it becomes prudent for the ESOH (J4E) to undertake any or all of these QA functions, the QAP will be revised accordingly. Only approved packaging shall be used for fissile material shipments. Changes to approved packaging are not permitted. Approved supporting documentation and/or documentation provided by the packaging supplier will be followed for use of the packaging. Items used in the assembly of the package are specified in the support documents and, if necessary, recorded to ensure that incorrect or defective items are not used.

10. Control of Special Processes

The ESOH (J4E) does not anticipate the undertaking of packaging design, fabrication, assembly, and proof of design testing. If in the future it becomes prudent for the ESOH (J4E) to undertake any or all of these QA functions, the QAP will be revised accordingly. If a special process is required for use of the supplied packaging, e.g. welding a container lid, then qualified personnel using qualified procedures in accordance with applicable codes, standards, specifications, criteria, and other special requirements will be specified in the approved supporting documentation and/or documentation provided by the packaging supplier.

11. Internal Inspection

The ESOH (J4E) does not anticipate the undertaking of packaging design, fabrication, assembly, and proof of design testing. If in the future it becomes prudent for the ESOH (J4E) to undertake any or all of these QA functions, the QAP will be revised accordingly. Approved supporting documentation will include inspections, as necessary, to be performed by personnel other than those performing the work or personnel performing the audit functions. Direct or indirect monitoring methods (electronic monitoring, measurements, tests and exams, etc.) may be used as specified in the approved supporting documentation by management, QA/QC and Inspection personnel, and Audit personnel.

12. Test Control

Testing of packaging at DTRA/SCC-WMD shall be limited as necessary to demonstrate that the packaging will function satisfactorily while loaded with the fissile material being shipped. Approved procedures specifying the tests to be performed and acceptance criteria shall be used. The approved procedures shall follow the pertinent requirements of the package approval. The approved procedures shall identify the testing equipment needed, provide for verification of calibration, and conclude with a statement of test results obtained. Test results shall be reviewed and accepted prior to making the fissile material shipment. Documentation of testing and the results obtained shall be included in the fissile material shipment records. Testing stated or implied herein shall not replace or negate the testing required to obtain NRC or DOT certification of the packaging.

13. Control of Measuring and Test Equipment

Measuring and testing under this QAP shall be limited to that necessary to verify that the package is ready and safe for use. Those items of equipment necessary for measurement and testing will be identified and the calibration maintained to the required accuracy, purpose, stability, and other conditions affecting measurement. Measuring and test equipment are calibrated at regular, specified intervals and calibration records are maintained. Portable radiological survey instruments are calibrated as required by 10 CFR 20. Prior to fissile material shipments made under this QAP, calibration status and operability of measurement and test equipment shall be determined and included in the shipment records and/or approved supporting documents.

14. Handling, Storage, and Shipping

As applicable, special handling, storage, shipping, cleaning, and preservation of materials and equipment to be used in packaging to prevent damage or deterioration shall be requested of the packaging supplier and included in approved supporting documentation. Special protective environment requirements shall be provided by the packaging supplier and specified in the approved related documents, as necessary. Additionally, particular attention will be given to advance agreement on the package receipt and on advance notification of the shipment. Approved supporting documents will include steps for coordination with state and federal officials, as necessary. Approved support documents will also identify any necessary shipping papers and notices to be included in the shipment.

15. Inspection, Test, and Operating Status

Markings (e.g. tags, labels, stamps, cards, etc.), affixed to packaging by the supplier to show evidence of satisfactory testing and operational status will not be removed or obliterated. Markings shall be affixed to packaging by the ESOH (J4E), as necessary to communicate the completion of inspections or testing in accordance with approved supporting documents, to preclude inadvertent bypassing of inspections or to communicate unserviceability.

16. Nonconforming Materials, Parts, or Components

Approved supporting documentation shall include information, as necessary, which:

a. Prevents inadvertent use or installation of materials, parts, or components that do not conform to the package requirements.

b. Identifies, documents, segregates, indicates disposition, and notifies affected organizations for nonconforming materials, parts, or components.

c. Provides criteria for the review and acceptance, rejection, repair, or rework of nonconforming materials, parts, or components.

17. Corrective Action

Conditions adverse to quality, such as deficiencies, deviations, defective material and equipment, and non-conformances, shall be reported by personnel to the QAPM for resolution. The QAPM or Site-RSO has the authority to cease operational functions with justifiable cause and shall

direct continuance of the operation only upon resolving the cause for the cessation of activities. Corrective actions must address the cause of the adverse conditions and preclude repetition and reported. Identified conditions adverse to quality, the cause of the condition, and corrective actions taken shall be documented by the QAPM and reported to the Chief, ERS, (J4EE).

18. Quality Assurance Records

Sufficient records shall be kept to describe the activities affecting quality. Records shall include all support documents and relevant specifications, such as required qualifications of personnel, procedures, and equipment. Also, copies of shipping papers, results of inspections, applicable test data, and audits that were completed shall be included in the records, as required. The QAPM will assume the responsibility as file custodian and will ensure documents are properly retained in accordance with the local filing plan and regulatory requirements. Records are kept for a minimum of 3 years beyond the last date in which the activity was performed. If any portion of an approved supporting document is superseded, the superseded material shall be retained for 3 years after it is superseded. Additionally, records will be retained as stated in the DTRA/SCC-WMD NRC license as applicable.

19. Audits

The Director, ESOH (J4E) shall ensure that audits are performed in accordance with pre-established written procedures or checklists and are conducted by qualified personnel not having direct responsibility in the areas being audited. The audit shall verify compliance with all aspects of the Quality Assurance program requirements and determine the effectiveness of the program. Transportation of DTRA/SCC-WMD fissile material sealed sources is expected to occur several times a month.

Accordingly, for the type, quantity, and form of the material, audits will occur annually during programmatic reviews but may be increased as needed to address deficiencies revealed during periodic or annual inspections. The frequency of audits shall be based on the importance of the activity to safety. It is the responsibility of the QAPM to ensure that corrective actions resulting from audits are completed and documented on a timely basis. Deficient areas shall be re-audited on a timely basis to verify implementation of corrective action(s). The results QAP for Packaging and Transportation of fissile material of the audit(s) will be provided to the Director, Acquisition, Finance, and Logistics (J48C); Chief, ERS (J4EE); QAPM; and Site-RSOs as appropriate.

As applicable, the QAPM shall ensure the maintenance of QA records are retained for the lifetime of packaging. Records showing evidence of delivery of packages to a carrier and proof that all NRC and DOT requirements have been satisfied shall also be retained.

If there are any questions or additional information needed, please contact Mr. Michael Hinton at (703) 767-0295 or email him at michael.hinton@dtra.mil

Sincerely,

Sherry J. Davis

Sherry J. Davis
Dir, ESOH Department (J4E)
Acquisition, Finance, &
Logistics
703-767-7122